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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,639

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Michael Cima

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03/18/2008

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/694,639	Applicant(s) CIMA ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The indicated allowability of claims 8-15 is withdrawn in view of the newly discovered reference(s) to Gerber (US 5,325,864); Alani et al.(US 4,390,027) and Counter (US 3,837,340). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Alani et al.(US 4,390,027); Rudiger et al.(US 4,887,611) or Gerber (US 5,325,864) in view of Counter (US 3,837,340).

All of the references of Alani et al., Rudiger et al. and Gerber disclose methods of using flexible substrates that includes providing a flexible substrate (See element (12) of Alani et al.; element (12) of Rudiger et al.; and element (2) of Gerber et al.) with a raised pad (See element (13) of Alani et al.; element (16) of Rudiger et al.; and element (5) of Gerber et al.) extending from the flexible substrate wherein the raised pad has a substantially planar sample receiving surface; depositing a sample on the raised pad (See element (14) of Alani et al.; element (17) of Rudiger et al.; and column 3, lines 35-38 of Gerber et al.); attaching the flexible substrate to an animal; and performing an experiment using the sample on the raised pad (See column 6, line 64, to column 7, line 3, of Alani et al.; column 4, lines 44-68, of Rudiger et al.; and column 5, lines 22-31 of Gerber et al.).

With respect to claim 8, while the references of Alani et al., Rudiger et al. and Gerber disclose the use of raised pads with planar surfaces, the raised pads also include a wall extending beyond and surrounding the planar surface.

The reference of Counter discloses that it is known in the art of transdermal application of substances to employ a flexible substrate (10) that includes a raised pad

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(30,40) having a planar surface with no wall extending beyond and surrounding the planar surface (See Figure 8).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sample receiving surfaces of the primary references such that they have no wall extending beyond and surrounding the planar surface for the known and expected result of providing an alternative means recognized in the art to achieve the same result, contacting a sample with the surface of an animal test subject. Use of the pad structure of Counter enables dried samples to be employed while maintaining efficient contact with test subject.

With respect to the sample preparation of claims 9-12, in the absence of a showing of criticality and/or unexpected results, it would have been with the purview of one having ordinary skill in the art to determine the optimum manner in which to provide the sample to the sample surface while maintaining the efficiency of the test device.

With respect to the method of manufacture of claims 13 and 14, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to construct the device based merely on considerations such as the material to be employed. Different materials require different manufacturing techniques.

With respect to claim 15, attaching the substrate to an animal results with the sample being overlayed with a membrane or tissue.

Allowable Subject Matter

6. Claims 16-18 are allowed.

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7. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 16-18, the claims are allowable because the prior art of record fails to teach or fairly suggest the use of a lower substrate member having an array of samples supported on raised pads with an overlay of a tissue specimen and an upper member defining a reservoir plate that defines an array of openings that align with the sample receiving surface of the lower substrate.

Response to Arguments

8. Applicant's remarks with respect to claims 8-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB